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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,562	12/22/2003	Remuga Gopal	NAA 0020 PA/41049.22	5054
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EXAMINER				
DANIELS, MATTHEW J				
ART UNIT		PAPER NUMBER		
1791				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/743,562

Applicant(s)

GOPAL ET AL.

Examiner

MATTHEW J. DANIELS

Art Unit

1791

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-14 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-14 and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 April 2008 has been entered.

Response to Amendment

2. The declaration filed on 26 August 2008 under 37 CFR 1.131 is sufficient to overcome the Bachmann reference. The declaration is signed by all members (pages 4-6), the activities occurred in a WTO country (paragraph 9), and the invention was reduced to practice prior to April 18, 2002 (paragraphs 6-8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Amendments to independent Claims 1, 19, and 21 which recite "separating the die from the orthodontic wire" are sufficient to overcome the rejections set forth previously.

Art Unit: 1791

4. **Claims 1-5, 7-8, 10-14, 17, 18, 21-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalnin (USPN 3674581) in view of Goldberg (USPN 4717341). **As to Claim 1**, Kalnin teaches a method of forming a wire, comprising:

placing a straight fiber material (2) in an elongate tunnel of a shrinkable die formed of a heat-sensitive material that shrinks in response to heat (1), the tunnel having a pre-defined transversal cross-sectional shape and having an open end;

shrinking the die by heating the die to reduce the transversal cross-section of the tunnel along a longitudinal extent of the tunnel so as to compress the fiber to assume the pre-defined transversal cross-sectional shape (8:33-42);

curing the composite of fiber and resin (8:60-70) and separating the die from the orthodontic wire (Fig. 5, 8:72);

wherein the tunnel assumes the pre-defined cross-sectional shape and size after said die is completely shrunk and shrinks uniformly in cross-sectional area as the die is shrunk (this aspect would have been obvious in that the initial tube, 1, has the same configuration as the shrunken tube, 6, suggesting that the shrinkage was uniform).

Kalnin is silent to (a) fabrication of an orthodontic wire, and (b) the order of steps of combining the fiber and resin material and placement into the elongate tunnel. However, these aspects of the invention would have been prima facie obvious for the following reasons:

(a) Kalnin provides a generic method for forming composites having oriented fibrous reinforcements in a thermosetting resin matrix, but merely fails to teach the claimed intended use. However, Goldberg teaches that it is known to provide composite materials having oriented fibrous reinforcements in a thermosetting resin matrix (Fig. 2, continuous graphite or glass, 8:24)

intended for use as arch wires (2:6-3:30). In view of the similar compositions, materials, and configurations, it is submitted that one of ordinary skill in the art would have recognized that the Kalnin article could be used as or modified into an arch wire for orthodontics.

(b) Kalnin teaches substantially the same steps, merely in a different order. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to rearrange the order of the steps disclosed in the Kalnin process. One would have recognized that the fibers would have been more easily impregnated prior to placement into the shrinkable tunnel than after shrinking of the shrinkable tunnel. Kalnin additionally teaches that such a rearrangement is known in the art (1:58-72), and would therefore have been obvious to the ordinary artisan and unpatentable.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Goldberg into that of Kalnin because Kalnin provides a generic method not limited to any particular end use, and in view of the similar compositions, materials, and configurations used in the Goldberg and Kalnin processes, it is submitted that one of ordinary skill in the art would have recognized that the Kalnin article could be used as or modified into an arch wire for orthodontics.

As to Claims 2 and 3, in the rearrangement of steps set forth in the rejection of Claim 1, it is further submitted that compression of the composite into a predetermined circular shape would have been obvious. The composite inherently retains its shape after separation from the tube. **As to Claim 4**, in the combination set forth above with respect to Claim 1, it is submitted that bent arch wires are conventional in providing arches (Goldberg, 4:61). **As to Claim 5**, two of the last steps performed by Kalnin are the steps of curing the resin material and removal of the

tube (8:61-72), and therefore in the combination set forth in the rejection of Claim 1, it is submitted that it would have been obvious to perform after the forming and shrinking. **As to Claims 7 and 8**, Kalnin provides strands longer than the tunnel and pulling them through the tunnel (Fig. 2). **As to Claims 10-12**, Kalnin provides the steps of pulling (Fig. 2), filling, and placement, and any order of performing these steps would have been obvious. There appears to be no unexpected result produced by the claimed orders or division of these steps over the Kalnin process. **As to Claim 13**, in view of the liquid depicted by Kalnin in Fig. 4, it is submitted that the tunnel or die is vertically disposed. **As to Claim 14**, in the combination set forth above with respect to Claim 1, Goldberg suggests possible applications for the Kalnin process. Since the Kalnin die or tube is polymeric (8:17-20), and would have obviously therefore been flexible, and because Goldberg suggests that oriented fiber materials are useful for arches (4:61), in the combination one would have found it obvious to perform a bending process to provide the arch shapes suggested by Goldberg. **As to Claim 17**, it is submitted that the shape and size of the article produced by the Kalnin process are defined by the die. **As to Claim 18**, as set forth above with respect to Claim 1, one of ordinary skill in the art would have recognized the utility of the article produced by the Kalnin process for use as an orthodontic wire in view of the Goldberg teachings. **As to Claims 22 and 23**, it is submitted that the Kalnin article would be biocompatible (carbon fiber and cured epoxy) and that the diameter of the resulting wire would have a diameter defined by the die when the die is completely shrunk. In the Kalnin process, since the tube compacts the fibers together (8:39-42), it is believed to be fully shrunk.

As to Claim 21, Kalnin teaches a method of forming a wire, comprising:

placing fibers (2) in an elongate tunnel of a shrinkable die formed of a heat-sensitive material that shrinks in response to heat (8:33-42), the tunnel having an opening (ends are open, Figs. 1-5);

shrinking the die by heating the die to reduce the transversal cross-section of the tunnel along a longitudinal extent of the tunnel so as to compress the fibers to assume a transversal cross-sectional shape defined by said tunnel of said die, wherein the tunnel assumes a pre-defined cross-sectional shape and size after the die is completely shrunk (item 6; 8:39-42);

curing the composite of fiber and resin to form a wire (8:60-70); and

separating said die from said orthodontic wire (Fig. 5; 8:72).

Kalnin is silent to (a) fabrication of an orthodontic wire, and (b) the order of steps of combining the fiber and resin material and placement into the elongate tunnel. However, these aspects of the invention would have been *prima facie* obvious for the following reasons:

(a) Kalnin provides a generic method for forming composites having oriented fibrous reinforcements in a thermosetting resin matrix, but merely fails to teach the claimed intended use. However, Goldberg teaches that it is known to provide composite materials having oriented fibrous reinforcements in a thermosetting resin matrix (Fig. 2, continuous graphite or glass, 8:24) intended for use as arch wires (2:6-3:30). In view of the similar compositions, materials, and configurations, it is submitted that one of ordinary skill in the art would have recognized that the Kalnin article could be used as or modified into an arch wire for orthodontics.

(b) Kalnin teaches substantially the same steps, merely in a different order. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to rearrange the order of the steps disclosed in the Kalnin process. One would have recognized that the fibers

would have been more easily impregnated prior to placement into the shrinkable tunnel than after shrinking of the shrinkable tunnel. Kalnin additionally teaches that such a rearrangement is known in the art (1:58-72), and would therefore have been obvious to the ordinary artisan and unpatentable.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Goldberg into that of Kalnin because Kalnin provides a generic method not limited to any particular end use, and in view of the similar compositions, materials, and configurations used in the Goldberg and Kalnin processes, it is submitted that one of ordinary skill in the art would have recognized that the Kalnin article could be used as or modified into an arch wire for orthodontics.

5. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalnin (USPN 3674581) in view of Goldberg (USPN 4717341) and further in view of Gray (USPN 5718251). Kalnin and Goldberg teach the subject matter of Claim 8 above under 35 USC 103(a). **As to Claim 9**, Kalnin teaches pulling at least one end (4), however, Kalnin and Goldberg are silent to pulling both ends to straighten the material in a die.

However, Gray teaches that in placing a material in a heat shrinkable sheath, it is desirable to place the ends under tension (Example 9, 10:65-11:22), or stated another way, to pull the fibers.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method Gray into that of Kalnin because use of the known Gray technique for fixing fibers in a desired orientation would have been obvious to improve the

similar or comparable Kalnin process in order to provide a predictable fixed and desired orientation of the fibers within the sheath.

6. **Claims 19 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalnin (USPN 3674581) in view of Goldberg (USPN 4717341) and Gray (USPN 5718251).

As to Claim 19, Kalnin teaches a method of forming a fiber reinforced composite comprising:

placing a plurality of elongate fiber strands (2) in a tunnel (1) of a shrinkable die formed of a heat-sensitive material that shrinks in response to heat (8:33-42), said tunnel extending longitudinally along an axis and having a pre-defined transversal cross-sectional shape and size and having an open end for allowing removal of excess resin (circle tube, open ends, Figs. 1-5);

pulling an end of said fiber strands to extend said fiber strands along said tunnel, generally parallel to said axis (4);

shrinking said die by heating said die to compress said fiber strands in said tunnel about said axis, to distribute said fiber substantially evenly within said tunnel, said fiber strands being compressed to assume said pre-defined transversal cross-sectional shape and size (8:33-42); and

curing the fiber and resin impregnant, to form said fiber reinforced composite orthodontic wire (8:60-70),

separating said die from said fiber reinforced composite wire (Fig. 5, 8:72),

wherein the tunnel assumes the pre-defined cross-sectional shape and size after said die is shrunk and shrinks uniformly in cross-sectional area as said die is shrunk (this aspect would have been obvious in that the initial tube, 1, has the same configuration as the shrunken tube, 6, suggesting that the shrinkage was uniform).

Kalnin is silent to (a) fabrication of an orthodontic wire, and (b) pulling (both) opposite ends of the fiber strand to orient, and (c) the order of steps of combining the fiber and resin material and placement into the elongate tunnel. However, these aspects of the invention would have been prima facie obvious for the following reasons:

(a) Kalnin provides a generic method for forming composites having oriented fibrous reinforcements in a thermosetting resin matrix, but merely fails to teach the claimed intended use. However, Goldberg teaches that it is known to provide composite materials having oriented fibrous reinforcements in a thermosetting resin matrix (Fig. 2, continuous graphite or glass, 8:24) intended for use as arch wires (2:6-3:30). In view of the similar compositions, materials, and configurations, it is submitted that one of ordinary skill in the art would have recognized that the Kalnin article could be used as or modified into an arch wire for orthodontics.

(b) Gray teaches that in placing a material in a heat shrinkable sheath, it is desirable to place the ends under tension (Example 9, 10:65-11:22), or stated another way, to pull the fibers.

(c) Kalnin teaches substantially the same steps, merely in a different order. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to rearrange the order of the steps disclosed in the Kalnin process. One would have recognized that the fibers would have been more easily impregnated prior to placement into the shrinkable tunnel than after shrinking of the shrinkable tunnel. Kalnin additionally teaches that such a rearrangement is known in the art (1:58-72), and would therefore have been obvious to the ordinary artisan and unpatentable.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the methods of Goldberg and Gray into that of Kalnin because (a)

Kalnin provides a generic method not limited to any particular end use, and in view of the similar compositions, materials, and configurations used in the Goldberg and Kalnin processes, it is submitted that one of ordinary skill in the art would have recognized that the Kalnin article could be used as or modified into an arch wire for orthodontics, and (b) use of the known Gray technique for fixing fibers in a desired orientation represents an improvement that one would have found obvious to apply to the Kalnin process in order to provide the desirable and predictable result that the fibers would be provided with a fixed and desired orientation sheath. **As to Claim 20**, in the combination set forth above with respect to Claim 19, Goldberg suggests possible applications for the Kalnin process. Since the Kalnin die or tube is polymeric (8:17-20), and would have obviously therefore been flexible, and because Goldberg suggests that oriented fiber materials are useful for arches (4:61), in the combination one would have found it obvious to perform a bending process to provide the arch shapes suggested by Goldberg.

Response to Arguments

7. Applicant's arguments, see the declaration filed 26 August 2008 and pages 7-8 of the arguments filed 9 April 2008, with respect to the pending rejections under 35 USC 103(a) have been fully considered and are persuasive. These rejections have been withdrawn.
8. However, upon further consideration, new rejections are set forth above.
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See "Fabrication of a new composite orthodontic archwire and validation by a bridging micromechanics model", *Biomaterials*, Vol. 24 (2003), pages 2941-2953. Applicants may wish to consider that the list of authors of the article is different than the inventors of the

instant application and that several of the references cited by the article have not been submitted for consideration in this application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. DANIELS whose telephone number is (571)272-2450. The examiner can normally be reached on Monday - Friday, 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J. Daniels/
Primary Examiner, Art Unit 1791
11/21/08